

(hereinafter referred to as "Yu"), further in view of U.S. Patent No. 5,690,924 of Keil, *et al.*, (hereinafter referred to as "Keil"), and the Examiner makes the rejection FINAL. It should be noted that all references to Wachter, both in Applicants' responses and in Papers No. 6 & No. 9, are directed to the column and line numbers of the English language equivalent of Wachter, U.S. Pat. No. 5,962,663.

The Examiner dismisses Applicants' arguments filed on August 26, 2002, as non-persuasive for a variety of reasons. The Examiner specifically argues that Applicants' arguments that "no references teach that [*sic*] the cosmetic compositions comprising ethanol in an amount of from 70-90% by weight, have been considered but not found persuasive since chitosan cosmetic compositions comprising ethanol in an amount of 40-50% by weight are known in the art." (See, Paper No. 9, p. 3). The Examiner argues that "the optimization of amounts of ethanol from 40-50% to 70-90% . . . is considered conventional in cosmetic science, well within the skill of artisan and involving merely routine skill in the art." (See, *id.*, at pp. 3-4 (*emphasis in original*)).

The Examiner also argues that the evidence set forth in the Specification at pages 12 and 13 thereof, fails to provide clear and convincing evidence of non-obviousness as there is "no comparison to the [cited prior art] present." (See, *id.*, at p.4).

On this basis the Examiner maintains the obviousness rejection and makes the rejection final. Applicants strenuously, but respectfully traverse the Examiner's rejection for the following reasons.

To begin with, as the Examiner has acknowledged, none of the three references, nor a combination thereof, teaches the claimed amount of ethanol. The Examiner argues that the use of the claimed amount is simply a routine optimization. Applicants again respectfully disagree with the Examiner's assessment.

First, obviousness rejections based upon optimization are appropriate only where the claimed subject matter is encompassed by the prior art. The M.P.E.P. specifically points out that, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. (See, M.P.E.P. §2144.05 II(A) (*emphasis added*)). In the

instant application, the claimed range of ethanol in the compositions according to the present invention is from 70 to 90% by weight. The cited references teach amounts of ethanol of 15%, 40% and 50% by weight. A range of from 70 to 90% by weight is NOT encompassed by the amounts of ethanol disclosed in the cited references. Moreover, there is no teaching or suggestion to use a greater amount of ethanol. The Examiner simply argues that ethanol is a known solvent for cosmetic compositions. This is not a suggestion to employ the claimed amount.

Second, "routine optimization" requires the identification of a result-effective variable. "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." (See, M.P.E.P. §2144.05 II(B) citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (*emphasis added*)). Nothing in the cited references recognizes ethanol concentration as a result-effective variable. Applicants have discovered and demonstrated that compositions containing chitosan salts and significantly larger amounts of ethanol result in greater flexural strength or "setting". This increase in setting is achieved through the use of high (from 70 to 90% by weight) concentrations of ethanol which require the use of chitosan salts exhibiting improved ethanol compatibility. This is exemplified in Table 1 of Applicants' Specification at page 13.

It is well-settled that in order to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

There is no suggestion in the cited references to employ greater amounts of

ethanol along with a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof. The cited prior art does not suggest that greater setting can be achieved by combining from 70-90% by weight ethanol and from 0.01 to 5% by weight of such a neutralization product. It cannot be said that such a modification is simply the routine optimization of a recognized result-effective variable.

Applicants reiterate all of the statements and arguments presented in their response filed on August 26, 2002. Nothing in any of the cited references teaches or suggests a cosmetic preparation comprising: (a) ethanol in an amount of from 70 to 90% by weight; and (b) a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product is present in an amount of from 0.01 to 5% by weight. There is simply no teaching to use such large amounts. Moreover, none of the cited references contains any teaching or suggestion which would motivate one of ordinary skill in the art to modify the teachings of the prior art to utilize significantly greater amounts of ethanol than taught in the cited references. Motivation for modification must suggest a desirability to the modification. None of the references contains any such teaching.

Finally, Applicants submit that the objective evidence contained in the Specification does in fact provide sufficient rebuttal to any alleged *prima facie* case of obviousness. The evidence set forth in Applicants' Specification shows that the claimed compositions, comprising 70-90% by weight of ethanol along with chitosan salts having increased ethanol compatibility, provide significant improvement in setting compared to a chitosan salt having lesser ethanol compatibility, and thus combined with less ethanol.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the objection and rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

CLAUDIA PANZER, et al.

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By: 

AARON R. ETTELMAN

Registration No. 42,516

COGNIS CORPORATION

2500 Renaissance Blvd., Suite 200

Gulph Mills, PA 19046

Telephone: (610) 278-4930

Facsimile: (215) 278-4971

E-Mail: AARON.ETTELMAN@COGNIS-US.COM

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